

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 1043		Date of mailing (day/month/year) 02 MAR 2005
International application No. PCT/US04/20296		FOR FURTHER ACTION See paragraph 2 below
International filing date (day/month/year) 25 June 2004 (25.06.2004)	Priority date (day/month/year) 27 June 2003 (27.06.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 38/00, 39/395; G01N 33/567 and US Cl.: 424/143.1; 435/7.21; 514/2		
Applicant TANOX, INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
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International application No.

PCT/US04/20296

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ in written format

☒ in computer readable form

c. time of filing/furnishing

☒ contained in international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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International application No.
PCT/US04/20296

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-25</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-25</u>	NO
Industrial applicability (IA)	Claims <u>1-25</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1 to 25 lack novelty under PCT Article 33(2) as being anticipated by the Rosen et al. patent publication. Rosen et al described an isolated receptor protein comprising the amino acid sequence presented therein as SEQ ID NO:45, of which residues 5 to 334 are identical to SEQ ID NO:2 of the instant description. Rosen et al. described an assay for the identification of agonists and antagonists of that receptor (para. 1329) as well as antibodies thereto (para. 0224), methods of treating (para. 0290, 0385) and diagnostic methods (para. 0388).

Claims 1 to 13 lack novelty under PCT Article 33(2) as being anticipated by the Arena Pharmaceuticals, Inc. patent publication. The Arena publication described an isolate receptor protein comprising the amino acid sequence presented in SEQ ID NO:36 of that publication, of which residues 5 to 334 are identical to SEQ ID NO:2 of the instant description. The entire Arena document is concerned with methods of identifying agonists, antagonists and inverse agonists to the receptor proteins described therein.

Claims 1 to 13 lack an inventive step under PCT Article 33(3) as being obvious over the Wittenberger et al. publication. The Wittenberger et al. publication described an isolate receptor protein comprising the amino acid sequence presented as hGPR91 in Figure 4(b) of that publication, of which is identical to SEQ ID NO:2 of the instant description. Given the description of an isolated nucleic acid encoding a human receptor protein, one of ordinary skill would have found it obvious to have employed a host cell comprising that nucleic acid in a process of identifying agonists and antagonists of the receptor protein encoded thereby by employing those methods that were in routine use in the art of receptor biology at the time that the Wittenberger et al. publication was published.